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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,073	06/16/2000	William J. Bologna	254/304	2949

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EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/17/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/596,073

Applicant(s)
Bologna

Examiner
Alton Pryor

Art Unit
1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 25, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10, and 14-30 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10, and 14-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7-9
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Applicant's arguments with respect to claim 1-7, 10, 14-30 have been considered but are moot in view of the new ground(s) of rejection.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

2. Claims 1,3-5,7,14-16,21-25,29,30 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Timpe et al (US 6063404; 5/16/00). Timpe teaches a method of delivering to a mammal a sex hormone (testosterone) comprising administering said hormone via a bioadhesive composition to a mucosal surface (mouth, vaginal, rectum) of the mammal wherein the composition is formulated as a tablet that includes

- (a) said hormone
- (b) a bioadhesive, water insoluble cross-linked polycarboxylic polymer (polycarbophil)
- (c) a water soluble polymer (carbopol).

Timpe does not specifically disclose that the prior art tablet would progressively hydrate. However since the prior art tablet is composed of the same ingredients as the instant tablet, it is inherent that the prior art tablet would also progressively hydrate at the time Timpe invention was

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made. See abstract, column 1 lines 22-44, column 2 lines 50-65, column 3 line 3 - column 4 line 40.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-7,10,14-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timpe above. Timpe teaches a method of delivering to a mammal a sex hormone (testosterone) comprising administering said hormone via a bioadhesive composition to a mucosal surface (mouth, vaginal, rectum) of the mammal wherein the composition is formulated as a tablet that includes

- (a) said hormone
- (b) a bioadhesive, water insoluble cross-linked polycarboxylic polymer (polycarbophil)
- (c) a water soluble polymer (carbopol).

Timpe does not specifically disclose that the prior art tablet would progressively hydrate. However since the prior art tablet is composed of the same ingredients as the instant tablet, it is obvious that the prior art tablet would also progressively hydrate at the time Timpe invention was made. See abstract, column 1 lines 22-44, column 2 lines 50-65, column 3 line 3 - column 4 line 40.

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Timpe does not teach the instant amount range of said hormone. However, one having ordinary skill in the art would have been expected to determine the optimum amounts through routine experimentation. One would have been motivated to do this in order to develop a method / composition that would deliver the optimum amount of said hormone to the mucosal surface.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton Pryor whose telephone number is (703) 308-4691. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Alton Pryor

Primary Examiner, AU 1616

12/12/01